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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,609	08/04/2000	Takeo Tanaami	000807	2753

7590 07/26/2002
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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,609

Applicant(s)

TANAAMI, TAKEO

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2002.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 April 2002 has been entered.
2. This action is in response to papers filed 25 March 2002 in Paper No. 7 in which claims 31-35 were canceled and claims 36-39 were added and papers filed 3 May 2002 in Paper No. 10 in which claims 36 and 38 were amended and claims 40 and 41 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 6 dated 5 February 2002 are maintained. All of the arguments have been thoroughly reviewed and discussed below. New grounds for rejection that address newly added limitations are discussed.

Currently claims 36-41 are under prosecution.

Claim Rejections - 35 USC § 112: First paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed composition/or methods are not described in the instant disclosure, claims 40 and 41 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The recitation "wherein said biomolecules are separated from said plurality of capillaries as extremely marginal droplets and then dribbled" is added to new claims 40 and 41. However, the specification fails to define "extremely marginal droplets" or "dribbled". Therefore, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

Claim Rejections - 35 USC § 112: Second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 36, 37, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36, 37 and 40 are indefinite in Claim 36 because the claim is drawn to a method of producing biochips, but the claim does not recite method steps of biochip production. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6. It is suggested that Claim 31 be amended to recite positive and active method steps of biochip production e.g. at the end of Claim 36 recite "to thereby produce said biochip."

Claims 40 and 41 are each indefinite for the recitation "extremely marginal droplets" because "extremely marginal" is a relative phrase which requires definition or criteria for determining. It is suggested that Claims 40 and 41 be amended to define or recite criteria for determining "extremely marginal" as described in the specification.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch U.S. Patent No. 6,083,763, issued 4 July 2000) in view of Haff et al. (U.S. Patent No. 5,720,923, issued 24 February 1998).

Regarding Claims 36, 37 and 41, Balch teaches a method for producing biochip comprising the steps of: arranging a plurality of capillaries having bottom open ends disposed at predetermined spacing so that said open ends are adjacent to and above a planar substrate, said open ends having a diameter which prevents biomolecules from dropping down by force of gravity (i.e. the capillaries must be primed to begin printing and therefore, biomolecules are prevented from dropping by force of gravity prior to priming, Column 15, lines 42-44), providing said biomolecules in said plurality of capillaries; applying voltage across said capillaries and substrate during the depositing to allow said biomolecules to move downward by force of attraction through said open ends to deposit said biomolecules onto said substrate at spaced intervals coinciding with said capillary spacing and stopping said voltage during non-depositing condition (i.e. the capillaries and reaction chambers are appropriately modified to maintain and modulate electro osmotic or electrophoretic potential, Column 15, lines 44-52) whereby accurate efficient control of said voltage applying causes uniform and reliable deposits of said biomolecules (Column 12, lines 13-29 and Claim 1) wherein said biomolecules are contained with said capillary and are DNA which is amplified i.e. PCR product is deposited onto the substrate (Column 35, lines 12-19 and Fig. 14) and wherein the biomolecules are deposited by applying a voltage across said capillary array i.e. electro-osmotic and/or electrophoretic force (Column 15, lines 48-50) and wherein the biomolecules are separated from said open ends of said capillaries as extremely marginal droplets and deposited onto said substrate (Column 15, lines 1-3) but they do not teach DNA contained within said capillary array is amplified within said capillaries by polymerase chain reaction. Haff et al. teach a similar method for producing an array of biomolecules wherein the biomolecules are deposited using a capillary array comprising a plurality of capillaries arranged in the same spacing interval as

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that of sites on the array and wherein the DNA within the capillary array is amplified within said capillaries by polymerase chain reaction (Column 4, lines 19-35 and Fig. 20) wherein the capillaries pass through "heat exchangers" to provide the required atmospheric temperature changes for the polymerase chain reaction (Column 18, lines 34-44 and Fig. 20 #212 and #213). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the PCR amplification of the DNA in the method of Balch by amplifying the DNA within their capillaries (Claims 31) by changing atmospheric temperature surrounding each capillary (Claim 32) to thereby very rapidly change the temperature of the capillary and PCR reaction within the capillary to greatly reduce the time required for the PCR reaction as taught by Haff et al. (Column 5, lines 27-33) for the obvious benefits of economy time and labor.

Regarding Claims 38, 39 and 41, Balch teaches the apparatus for producing biochips comprising: plurality of capillaries having bottom open ends arranged at a same spacing interval as that of sites on a planar substrate (i.e. capillary sleeve/array template, Column 12, lines 63-67) wherein said open ends have a diameter which prevents biomolecules from dropping down by force of gravity (i.e. the capillaries must be primed to begin printing and therefore, biomolecules are prevented from dropping by force of gravity prior to priming, Column 15, lines 42-44); adjusting means for adjusting a gap formed between said capillary holder means and said substrate i.e. print head and positioning device (Column 15, lines 26-37 and Claim 7); transfer means for transferring biomolecules from said capillaries to said substrate and enabling said biomolecules to remain in said plurality of capillaries during non-depositing state (i.e. the capillaries and reaction chambers are appropriately modified to maintain and modulate electro osmotic or electrophoretic potential, Column 15, lines 44-52) whereby accurate efficient control of said voltage applying causes uniform and reliable deposits of said biomolecules (Column 12, lines 13-29 and Claim 1) and voltage means for applying voltage across said capillary holder means e.g. electro-osmotic or electrophoretic force (Column

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15, lines 44-52 and Claims 15, 18 and 19); whereby accurate efficient control of said voltage applying causes uniform and reliable deposits of said biomolecules (Column 12, lines 13-29 and Claim 1) and wherein the biomolecules are separated from said open ends of said capillaries as extremely marginal droplets and deposited onto said substrate (Column 15, lines 1-3). Additionally, Balch teach a PCR product is deposited onto the substrate (Column 35, lines 12-19 and Fig. 14) but they do not teach their apparatus comprises means for amplifying DNA in said capillaries by polymerase chain reaction. Haff et al. teach a similar apparatus for producing an array of biomolecules comprising a holder means for supporting a plurality of capillaries arranged in the same spacing interval as that of sites on the array (i.e. clamp bar, Fig. 20 # 234); means for adjusting a gap formed between said capillary holder and substrate (i.e. tube lift assembly, Fig 20, # 236); and means for transferring biomolecules from said capillaries to said substrate (i.e. plungers, Fig. 20 #266) and further comprising means for amplifying DNA in said capillaries by PCR (Column 4, lines 19-35 and Fig. 20) wherein the capillary PCR simplifies the PCR reaction by reducing thermal gradient problems and shortens the PCR reaction time by providing for very rapid temperature changes (Column 5, lines 11-16 and 28-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus comprising capillary sleeve/array template through which the capillaries are spatially arrayed and controlled in the method of Balch (Column 12, lines 63-67) by incorporating a heat exchanging capillary sleeve/array template as taught by Haff et al. which also arrays and controls the capillaries but additionally provides the environment for amplifying DNA in the capillary by PCR to thereby provide and deposit PCR products rapidly and accurately as taught by Haff et al. (Column 5, lines 7-35) for the expected benefit of making continuous the amplification and deposition of the biomolecules into a single unified apparatus. The courts have stated that continuous operation of multiple process steps is obvious in view of the prior art teaching of the batch process (see *In re Dilnot*, 319 F.2d 188, 138 USPQ 248 (CCPA 1963 and MPEP, 2144.04 E.).

Response to Arguments

9. Applicant argues that the instant invention differs from Balch in that Balch turns on electric current thorough solution after the solution has come into contact with the substrate. Applicant's interpretation of Balch has been considered but is not found persuasive because Applicant does not point of this teaching in Balch and because the recitation pointed to by the examiner does not teach when the electric current is turned on or off. Balch teach that the do they teach that the capillaries and reaction chambers are appropriately modified to maintain and modulate electro osmotic or electrophoretic potential, Column 15, lines 44-52) but they do not specifically teach when the voltage is turned on or off.

Applicant further argues that the instant invention differs from Balch in that the instant invention: the capillaries and substrate are kept at all times apart form each other so that no current flows; voltage is applied across the capillary and substrate so that electric fields are produced; a very small volume of the solution is then made to swell out of the bottom and by force of [electrical] attraction be deposited onto the substrate; [electrical] attractive forces between the solution and the substrate before contact occurs; PCR is speeded up using thinner capillaries. This argument has been considered but is not found persuasive because the argument addresses limitations not in the claims. Specifically, the claims do not recite: the capillaries and substrate are kept apart at all times; electric fields are produced; solution is made to swell out of the bottom of the capillary by force of electrical attraction; attractive forces between solution and substrate occurs before contact.

The examiner aggress that Balch does not teach many of the above elements. Claims amended to recite the above elements would overcome the teaching of Balch. Amendments reciting the limitations described on page 10, lines 17-page 11, line 12 of the specification would overcome the Balch reference e.g. the capillaries and substrate are kept at all times apart from each other so that no current flows; the diameter of the capillaries provides a

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solution surface tension greater than gravitational force; voltage is applied across the capillary and substrate so that the capillary and substrate are oppositely charged; a very small volume of the solution is then made to swell out of the bottom and by force of [electrical] attraction be deposited onto the substrate; [electrical] attractive forces between the solution and the substrate before contact occurs.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 36 and 38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of copending Application No. 09/792,967. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method of producing biochip wherein biological polymers are deposited onto a substrate using a capillary array comprising a plurality of capillaries having the same spacing interval as that of sites on the substrate, wherein the biological polymers are DNA which are amplified within the capillaries using the polymerase chain reaction (PCR) wherein the PCR is performed at atmospheric temperature or by heating by laser irradiation and wherein the samples are deposited by applying voltage across the capillary array and substrate. The sets of claims differ only in the arrangement or grouping of the limitations and terminology e.g. the '967 set recites

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"wherein said DNA is amplified within said capillaries by polymerase chain reaction" and the instant set recites "providing polymerase chain reaction to amplify said biomolecules within said plurality of capillaries". Because both sets of claims are essentially the same being drawn to the same invention and differ only in the arrangement of the limitation, the instant claims are obvious over the '967 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 5, 2002